

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC.,

Plaintiff,

v.

DEXCOM, INC.,

Defendants.

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C.A. No. 05-590 GMS

MEMORANDUM

I. INTRODUCTION

On August 11, 2005, Abbott Diabetes Care, Inc. (“Abbott”) brought this declaratory judgment (Count I) and patent infringement (Count II) action against DexCom, Inc. (“DexCom”). Presently before the court are the following motions: (1) DexCom’s Motion to Dismiss Abbott’s Complaint (D.I. 5); (2) DexCom’s Motion to Strike the “Amended Complaint” and Renewed Motion to Dismiss Abbott’s Complaint (D.I. 61); and (3) DexCom’s Motion to Stay Pending Reexamination of the Patents-in-suit (D.I. 25). For the reasons that follow, the court will grant in part and deny in part DexCom’s motion to dismiss. The court will grant the motion to dismiss Abbott’s declaratory judgment count and will deny the motion to dismiss the infringement count. Additionally, the court will grant DexCom’s motion to strike the “amended complaint,” deny the renewed motion to dismiss the complaint as moot, and grant the motion to stay pending reexamination of Abbott’s patents.

II. BACKGROUND

Abbott owns U.S. Patent Nos. 6,175,752 (the “‘752 patent”), 6,284,478 (the “‘478 patent”), 6,329,161 (the “‘161 patent”), and 6,565,509 (the “‘509 patent”) (collectively, the “patents-in-suit”). The patents-in-suit are directed to methods, systems, and devices for continuously monitoring glucose levels in humans. (Compl. ¶ 7.) The patented technology at issue offers an alternative monitoring system for diabetics, who currently monitor their glucose levels by pricking their fingers to draw blood several times a day. (D.I. 32, at 3; see ‘752 patent, Col. 1, ll. 21-26; ‘509 patent Col. 1, ll. 21-26.) According to the background of the invention sections of the ‘752 and ‘509 patents, the pricking technique does not permit the continuous monitoring of glucose, is painful and inconvenient, and results in inconsistencies in monitoring among individuals with diabetes. (See ‘752 patent, Col. 1, ll. 26-38; ‘509 patent, Col. 1, ll. 26-38.) Therefore, the technology described in the patents-in-suit was invented to address the need for a small and comfortable device that could continuously monitor glucose levels for days at a time, while permitting a patient to engage in normal activities. (‘752 patent, Col. 2, ll. 1-4; ‘509 patent, Col. 2, ll. 5-8.) Each of the patents-in-suit relate to an aspect of the continuous glucose monitor, which involves implanting a glucose sensor in a patient and monitoring signals over the life of the sensor.¹ (D.I. 32, at 3.) The monitoring device provides patients with feedback regarding their glucose levels, and may even include an alarm to warn patients of dangerous glucose levels. (Id. at 3-4.)

Abbott alleges that DexCom intends to market its STS™ Continuous Glucose Monitoring System, which will infringe one or more claims of the patents-in-suit. The complaint states that DexCom filed a premarket approval application with the Food and Drug Administration (the

¹ The ‘752 and ‘509 patents relate to glucose monitoring devices and their methods of use, while the ‘478 and ‘161 patents relate to subcutaneous glucose sensors.

“FDA”) in March 2005, seeking approval to sell its product. (Compl. ¶ 12.) The complaint further states that DexCom expects FDA approval by the second quarter of 2006.² (Id. ¶ 15.) In Count I, Abbott seeks declaratory relief in the form of a judicial declaration that DexCom’s product will infringe one or more claims of each of the patents-in-suit. (Id. ¶ 25.)

Further, Abbott alleges that, prior to filing its premarket approval application with the FDA, DexCom attended two “trade shows” where it publicized and displayed its glucose monitoring product. (Compl. ¶ 16.) The complaint alleges that the products DexCom displayed at the trade shows were manufactured for the purpose of showcasing rather than for gathering information for submission to the FDA. (Id. ¶ 17.) Abbott alleges that DexCom’s manufacture and display of its product constitutes an act of patent infringement. (Id. ¶ 28.)

On August 31, 2005, DexCom filed a motion to dismiss Abbott’s complaint for lack of subject matter jurisdiction and failure to state a claim. Additionally, on February 22, 2006, DexCom filed a motion to stay the litigation pending reexamination of the patents-in-suit. On June 27, 2006, Abbott filed an amended complaint, which alleges further infringing acts on the part of DexCom and adds several patents to the suit. On July 12, 2006, DexCom filed a motion to strike the “amended complaint” and renewed motion to dismiss.

III. DISCUSSION

² As previously mentioned, Abbott filed its complaint on August 11, 2005. The FDA subsequently approved DexCom’s glucose monitoring product, in March 2006.

A. Motion to Dismiss for Lack of Subject Matter Jurisdiction

Dexcom first contends that the court should dismiss Abbott's declaratory judgment claim because there is currently no "accused device" to compare against the claims of the patents-in-suit and, therefore, Abbott's claim is premature. In other words, DexCom contends the court lacks subject matter jurisdiction over Count I of Abbott's Complaint.

A motion to dismiss under Rule 12(b)(1) of the Federal Rules of Civil Procedure contests the jurisdiction of the Court to address the merits of a plaintiff's complaint. Such a challenge may present either a facial or a factual contest to subject matter jurisdiction. *See Mortensen v. First Fed. Sav. and Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). When asserting a facial challenge, a defendant contends that the complaint alleges facts that, even if true, would be insufficient to establish the Court's jurisdiction. *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). The present motion presents a facial challenge to the complaint because the jurisdictional facts are not in dispute. Such a motion requires the court to consider the allegations of the complaint as true and to make all reasonable inferences in the plaintiff's favor. *See id.* Additionally, the court must test the existence of jurisdiction as of the time the complaint was filed. *Lang v. Pacific Marine and Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990).

The Declaratory Judgment Act (the "Act") provides that "[i]n a case of actual controversy . . . [a court of competent jurisdiction] may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). Thus, before a court may exercise jurisdiction over a declaratory judgment action, the Act requires an "actual controversy between the parties." *Medimmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376, 1378-79 (Fed. Cir. 2005) (citing *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d

1324, 1331 (Fed. Cir. 2005)). “If the controversy requirement is met by a sufficient allegation of immediacy and reality . . . a patentee [is able] to seek a declaration of infringement against a future infringer . . . [just as] a future infringer is able to maintain a declaratory judgment action of noninfringement under the same circumstances.” *Telectronics Pacing Sys., Inc v. Ventritrex, Inc.*, 982 F.2d 1520, 1526 (Fed. Cir. 1992) (citing *Lang*, 895 F.2d at 764).

However, a district court does not have jurisdiction to hear the action when there is no actual controversy. *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991), *cert. denied*, 112 S. Ct. 658 (1991). Moreover, “even assuming [the existence of] an actual controversy, the exercise of a court’s jurisdiction over a declaratory judgment action is discretionary.” *Telectronics*, 982 F.2d at 1526 (citations omitted).

Two elements must be present in order to meet the controversy requirement in a declaratory judgment action brought by a patentee against an alleged future infringer: (1) the defendant must be engaged in an activity directed toward making, selling, or using subject to an infringement charge under 35 U.S.C. § 271(a), or be making meaningful preparation for such activity; and (2) acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming. *Lang*, 895 F.2d at 764. In addition, the declaratory judgment plaintiff bears the burden of proving the existence of facts underlying its allegations of the existence of an actual controversy. *Jervis B. Webb Co. v. S. Sys., Inc.*, 742 F.2d 1388, 1399 (Fed. Cir. 1984).

Applying the above-discussed elements to the present case, it is clear to the court from the

record before it that Abbott's complaint did not present an actual controversy under the Act at the time it was filed. That is, Abbott has not demonstrated that DexCom produced or has prepared to produce a product that would be subject to an infringement charge under 35 U.S.C. § 271. At the time Abbott filed its complaint, the FDA had not approved DexCom's product and Abbott could not predict when, or if, the FDA would approve the product. Indeed, Abbott states as much in its complaint, alleging that "DexCom . . . *expects* FDA approval for marketing by the second quarter of 2006. . . ." (Compl. ¶ 15) (emphasis added).³ Additionally, Abbott did not, and could not, allege with any certainty that "the device when approved would be the same device that began clinical trials[.]" as "product changes during testing are contemplated by statute, 21 U.S.C. § 360j(g)(2)(C)(iii) (1988)." *Telectronics*, 982 F.2d at 1527. Most important, Abbott did not allege nor does it now contend that DexCom has distributed sales literature, prepared to solicit orders, or engaged in any sales or marketing activity with regard to its glucose monitoring product. *See Lang*, 895 F.2d at 765; *Benitec Australia Ltd. v. Nucleonics, Inc.*, Civil Action No. 04-0174 JJF, 2005 U.S. Dist. LEXIS 22008, at *9 (D. Del. Sept. 29, 2005); *Interdigital Tech. Corp. v. OKI Am., Inc.*, 845 F. Supp. 276, 284 (E.D. Pa. 1994) ("Activity directed towards advertising or marketing the accused device is particularly important to a finding of a justiciable controversy.") Therefore, the court concludes that no controversy of sufficient immediacy and reality existed, at the time Abbott filed its complaint, to support declaratory judgment jurisdiction in the present case. As such, the court will dismiss Count I of Abbott's complaint.

³ The court agrees with the argument Abbott makes in its answering brief, namely that FDA approval is not the standard by which it should evaluate whether an actual controversy existed at the time the complaint was filed. However, the court finds that the absence of FDA approval is evidence that the dispute between the parties is neither real nor immediate.

B. Motion to Strike Abbott's "Amended Complaint"

DexCom next argues that the court should strike the "Amended Complaint" because Abbott failed to seek leave of court to file what correctly should be termed a "supplemental pleading." Conversely, Abbott asserts that it properly amended its complaint under Federal Rule of Civil Procedure 15(a) to allege additional acts of infringement that occurred prior to and after it filed the initial complaint. The court is unpersuaded by Abbott's argument and will, therefore, strike its "Amended Complaint."

As Abbott points out in its briefing, "[a]n amended pleading generally is a modification to incorporate events that were unknown but occurred *prior* to the filing of the original pleading." (D.I. 66, at 7) (emphasis added) (citing 3 James Wm. Moore et al., Moore's Federal Practice § 15.02 (3d ed. 1999)). On the other hand, "a supplemental pleading refers to additions to include transactions or occurrences that take place after the filing of the original pleading." (D.I. 66, at 7.) By Abbott's own words, it amended its complaint "to allege additional acts of infringement that occurred prior to and *after*" its initial complaint. (Id.) Because Abbott's "Amended Complaint" contains allegations regarding events that occurred after August 11, 2005 – the filing date of the original complaint – it is governed by Federal Rule of Civil Procedure 15(d). Pursuant to Rule 15(d), "[u]pon motion of a party the court may, upon reasonable notice and upon such terms as are just, permit the party to serve a supplemental pleading setting forth transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented. Fed. R. Civ. P. 15(d); *see GAF Bldg. Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 483 (Fed. Cir. 1996) (holding that district court did not abuse its discretion when "adhering to the motion requirement of Rule 15"); *Bronson v. Horn*, Civil Action No. 02-663, 2006 U.S. Dist. LEXIS 38791, at *5 (W.D.

Pa. June 12, 2006) (dismissing supplemental complaint because it was not filed pursuant to a motion). Accordingly, because Abbott did not file a motion to supplement its complaint in the present case, the court will strike it from the docket for failure to comply with Rule 15(d).

C. Motion to Dismiss for Failure to State a Claim

Finally, with respect to dismissal, DexCom contends that Count II of Abbott's complaint fails to state a claim for which relief can be granted. According to DexCom, its display of glucose monitoring products at two scientific conferences is exempt under 35 U.S.C. § 271(e)(1).⁴ Therefore, DexCom argues that Abbott has failed to state a claim for patent infringement.

The purpose of a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) is to test the sufficiency of a complaint, not to resolve disputed facts or decide the merits of the case. *See Kost v. Kozakiewicz*, 1 F.3d 183 (3d Cir. 1993). Thus, in deciding a motion to dismiss, the factual allegations of the complaint must be accepted as true. *See Graves v. Lowery*, 117 F.3d 723, 726 (3d Cir. 1997); *Nami v. Fauver*, 82 F.3d 63, 65 (3d Cir. 1996). In particular, the court looks to "whether sufficient facts are pleaded to determine that the complaint is not frivolous, and to provide defendants with adequate notice to frame an answer." *Colburn v. Upper Darby Twp.*, 838 F.2d 663, 666 (3d Cir. 1988). However, the court need not "credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss." *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902,

⁴ Section 271(e)(1) states, in pertinent part:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. 271(e)(1).

906 (3rd Cir.1997). A court should dismiss a complaint “only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.” *See Graves*, 117 F.3d at 726; *Nami*, 82 F.3d at 65 (both citing *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957)). Thus, in order to prevail, a moving party must show “beyond doubt that the plaintiff can prove no set of facts in support of his claim [that] would entitle him to relief.” *Conley*, 355 U.S. at 45-46.

After having reviewed Abbott’s complaint, the parties’ submissions and relevant case law, the court concludes that DexCom cannot show that “beyond doubt” there exists “no set of facts” in support of Abbott’s patent infringement claim. The language of section 271(e)(1) exempts potentially infringing activities “if performed solely for uses reasonably related to the development of information for FDA approval.” *Telectronics*, 982 F.2d at 1523. Here, Abbott’s complaint alleges that “[u]pon information and belief, the [DexCom] products displayed at the [two] trade shows were manufactured for the purpose of showcasing at the trade shows rather than for the purpose of gathering information.” (Compl. ¶ 17.) Abbott’s complaint, therefore, alleges that DexCom’s manufacture and display of products at scientific conferences or trade shows falls outside the safe harbor of section 271(e)(1). Based upon this allegation, and viewing the complaint in the light most favorable to Abbott, the court is unwilling to conclude at this juncture that no relief could be granted under any set of facts that Abbott could prove consistent with its patent infringement allegations.⁵ Therefore, the court will deny DexCom’s motion to dismiss Count II of the complaint.

⁵ DexCom contends that the facts of the present case are on “all fours” with the facts of *Telectronics*. The court, however, finds that DexCom’s reliance is misplaced because, in *Telectronics*, the Federal Circuit reviewed a district court’s grant of summary judgment for the defendant, while here the court must decide a motion to dismiss. As DexCom well knows, the standard for granting a motion to dismiss is markedly different from the summary judgment standard. When deciding a Rule 56 motion, the court reviews “the pleadings, *depositions*, *answers to interrogatories*, and *admissions on file*, together with [any] affidavits,” to determine

D. Motion to Stay

DexCom has also filed a motion to stay the litigation pending reexamination of the patents-in-suit by the Patent and Trademark Office (the “PTO”). The decision to stay a case is firmly within the discretion of the court. *See Cost Bros., Inc. v. Travelers Indem. Co.*, 760 F.2d 58, 60 (3d Cir. 1985). This authority applies equally to patent cases in which a reexamination by the PTO has been requested. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988) (noting that “[c]ourts have inherent power to manage their dockets and stay proceedings, including the authority to order a stay pending conclusion of a PTO reexamination.”) (internal citations omitted). In determining whether a stay is appropriate, the court’s discretion is guided by the following factors: “(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set.” *Xerox Corp. v. 3 Com Corp.*, 69 F. Supp. 2d 404, 406 (W.D.N.Y. 1999) (citing cases); *cf. United Sweetener USA, Inc. v. Nutrasweet Co.*, 766 F. Supp. 212, 217 (D. Del. 1991) (stating a similar test).

In opposing DexCom’s motion, Abbott maintains that a stay would prevent it from seeking

whether “there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c) (emphasis added). In contrast, when deciding a motion to dismiss, the scope of the court’s review is limited to the complaint. *See Pryor v. Nat’l Collegiate Athletic Ass’n*, 288 F.3d 548, 560 (3d Cir. 2002) (“As a general rule, the court may only consider the pleading that is attacked by an FRCP 12(b)(6) motion in determining its sufficiency.”) Therefore, *Telectronics* is distinguishable in that the court made its determination after reviewing a more complete record than that which the court is permitted to review here. That is not to say that DexCom could not successfully attack Abbott’s claim at a later stage of these proceedings. For example if, through discovery, DexCom adduces facts indicating that its conduct at the scientific conferences or trade shows falls within the section 271(e)(1) safe harbor, the court will likely entertain a motion for summary judgment at the appropriate time.

a preliminary injunction and enforcing its patent rights, thereby unduly prejudicing it and presenting it with a clear tactical disadvantage in the marketplace. The court is not persuaded. First, Abbott's argument is premised on its filing of a motion for preliminary injunction. Abbott, however, did not, and has not, filed any such motion, even though the FDA has recently approved DexCom's glucose monitoring product for marketing. Because Abbott has not filed a motion for preliminary injunction, its arguments relating to the court's rendering of an opinion on such a motion are moot. As such, the only other argument Abbott asserts with respect to undue prejudice is that it will be unable to enforce its patents while in reexamination. Abbott's position, however, assumes that the PTO will leave all of the more than 200 claims of the four patents-in-suit unaltered after reexamination. *See Applera Corp. v. Thermo Electron Corp.*, No. C.A. 04-1230 GMS, (D. Del. Dec. 28, 2005) (04-1230 D.I. 81 ¶ 6). Further, while Abbott may suffer some prejudice from a stay, the court is not persuaded that a stay would *unduly* prejudice Abbott, or present any clear tactical disadvantage. Accordingly, the first factor militates in favor of granting the requested stay.

With respect to the second factor, Abbott argues that a stay will not simplify the issues, but prolong the litigation. According to Abbott, the only way to avoid prolonging the litigation would be if the reexamination resulted in the PTO invalidating all of the asserted claims of all of the patents-in-suit. The court cannot agree. Contrary to Abbott's position, the court finds that granting the stay will simplify the issues and focus the litigation. For example, if the PTO determines that some or all of the claims of the of the four patents undergoing reexamination are invalid, then many of the issues in the litigation will become moot. Additionally, it is beyond dispute that the court, as well as the parties, would benefit from a narrowing of the variety of complex issues relating to the numerous claims at issue, which, if clearly defined, would streamline the discovery process and the

remainder of the litigation. A stay, therefore, will conserve the resources of the parties and the court, thereby promoting efficiency. Moreover, the court would not run the risk of inconsistent rulings or issuing advisory opinions. *See Gioello Enters. Ltd. v. Mattel, Inc.*, No. C.A. 99-375 GMS, 2001 WL 125340, at *1 (D. Del. Jan. 29, 2001). The second factor, therefore, weighs in favor of granting the motion to stay.

Finally, the court finds that the third factor it must consider in its determination, i.e. whether discovery is complete and whether a trial date has been set, weighs in favor of granting the motion. In the present case, fact discovery is not scheduled to close until January 31, 2007 and, although already set, the trial is not scheduled to begin until October 9, 2007.⁶ Thus, given its findings with respect to the first two factors, the court concludes that the balance of harms weighs in favor of granting a stay of this action. Accordingly, the court will grant DexCom's motion to stay.

Dated: August 16, 2006

/s/ Gregory M. Sleet
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

⁶ See Amended Scheduling Order, D.I. 71 ¶¶ 2, 8.

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ORDER

For the reasons stated in the court's Memorandum of this same date, IT IS HEREBY ORDERED that:

1. The defendant's Motion to Dismiss Abbott's Complaint (D.I. 5) is GRANTED in part and DENIED in part. The motion is GRANTED with respect to Count I of Abbott's complaint and DENIED with respect to Count II of Abbott's complaint.
2. The court shall dismiss Count I of Abbott's complaint without prejudice.
3. The plaintiff's Motion For Limited Jurisdictional Discovery and for a Corresponding Extension of the Briefing Schedule on DexCom's Motion to Dismiss (D.I. 9) is DENIED as moot.
4. The defendant's Motion to Strike the "Amended Complaint" and Renewed Motion to Dismiss Abbott's Complaint (D.I. 61) is GRANTED in part and DENIED in part. The motion to strike the "amended complaint" is GRANTED and the renewed motion to dismiss is DENIED as moot.
5. The plaintiff's Amended Complaint (D.I. 55) shall be stricken from the court's docket.

6. The defendant's Motion to Stay Pending Reexamination of the Patents-in-suit (D.I. 25) is GRANTED.

Dated: August 16, 2006

/s/ Gregory M. Sleet
UNITED STATES DISTRICT JUDGE